

EXHIBIT A

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Drug Information: Bacillus Calmette-Guerin (BCG) VaccineURL of this page: <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a682809.html>

(ba sil' us kal' met gay rayn')

WHY is this medicine prescribed?

BCG vaccine provides immunity or protection against tuberculosis (TB). The vaccine may be given to persons at high risk of developing TB. It is also used to treat bladder tumors or bladder cancer.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

HOW should this medicine be used?

Your doctor or a health care provider will administer this medicine. When used to protect against TB, it is injected into the skin. Keep the vaccination area dry for 24 hours after receiving the vaccine, and keep the area clean until you cannot tell the vaccination area from the skin around it.

When used for bladder cancer, the medicine flows into your bladder through a tube or catheter. Avoid drinking fluids for 4 hours before your treatment. You should empty your bladder before treatment. During the first hour after the medication is infused, you will lie on your stomach, back, and sides for 15 minutes each. Then you will stand, but you should keep the medication in your bladder for another hour. If you cannot keep the medication in your bladder for the entire 2 hours, tell your health care provider. At the end of 2 hours you will empty your bladder in a seated manner for safety reasons. Your urine should be disinfected for 6 hours after the medication is administered. Pour a similar amount of undiluted bleach in the toilet after you urinate. Let it stand for 15 minutes before flushing.

Various dosing schedules may be used. Your doctor will schedule your treatment. Ask your doctor to explain any directions you do not understand.

When the vaccine is given to protect against TB, it usually is given only one time but may be repeated if there is not a good response in 2-3 months. Response is measured by a TB skin test.

What SPECIAL PRECAUTIONS should I follow?

Before receiving BCG vaccine,

- tell your doctor and pharmacist if you are allergic to BCG vaccine or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially antibiotics, cancer chemotherapy agents, steroids, tuberculosis medications, and vitamins.
- tell your doctor if you have had a recent smallpox vaccination or if you have had a positive TB test.
- tell your doctor if you have an immune disorder, cancer, fever, an infection, or an area of severe burns on your body.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking BCG vaccine, call your doctor immediately.

What SIDE EFFECTS can this medicine cause?

BCG vaccine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- swollen lymph nodes
- small red areas at the site of injection. (These usually appear 10-14 days after injection and slowly decrease in size. They should disappear after about 6 months.)
- fever
- blood in the urine
- frequent or painful urination
- upset stomach
- vomiting

If you experience any of the following symptoms, call your doctor immediately:

- severe skin rash
- difficulty breathing or swallowing
- wheezing

What should I do in case of OVERDOSE?

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What OTHER INFORMATION should I know?

Keep all appointments with your doctor and the laboratory.

Brand name(s):

- TheraCys® BCG
- TICE® BCG

Other name(s):

- BCG live
- BCG vaccine

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